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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,068

Applicant(s)

MAGINOT, THOMAS J.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-262 is/are pending in the application.
- 4a) Of the above claim(s) 6-84 and 202-259 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 1-4, 85-201 and 260-262 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/5/04 + 2/3/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 3738

Election/Restrictions

Applicant's election of Group I in the reply filed on February 3, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6-84 and 202-259 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 260-263 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,599,313. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more detailed and limited, but

Art Unit: 3738

the present claims are read on thereby. For this reason, the present claims are considered to be clearly obvious in view of the patented claims.

Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5 of copending Application No. 10/726,803 in view of Redtenbacher et al (US 4,817,847). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are narrowing in scope than the present claims but are read on by the present claims except for the "endoscopic" instrument use. However, Redtenbacher teaches that endoscopic use during similar anastomosis procedures was known; see column 3, lines 16-25 and the paragraph bridging columns 6 and 7. Therefore, it is the Examiner's position that it would have been obvious to use an endoscope in the procedure of the copending claims for the same reasons that Redtenbacher uses the same and in order to perform the procedure with greater accuracy and precision.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/824,043 in view of Redtenbacher et al (US 4,817,847). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are narrowing in scope than the present claims but are read on by the present claims except for the "endoscopic" instrument use. However,

Art Unit: 3738

Redtenbacher teaches that endoscopic use during similar anastomosis procedures was known; see column 3, lines 16-25 and the paragraph bridging columns 6 and 7.

Therefore, it is the Examiner's position that it would have been obvious to use an endoscope in the procedure of the copending claims for the same reasons that Redtenbacher uses the same and in order to perform the procedure with greater accuracy and precision.

This is a provisional obviousness-type double patenting rejection.

Terminal Disclaimer

The terminal disclaimer filed February 3, 2005 is not proper. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

Claim Objections

Claim 191 is objected to because of the following informalities: On lines 2, 4, and 7 of claim 191, "the passageway" lacks clear antecedent basis from claim 186. Appropriate correction is required.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

Art Unit: 3738

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 261 is rejected under 35 U.S.C. 102(e) as being anticipated by Wilk (US 5,261,861). Wilk anticipates the claim language where the medical instrument as claimed is the catheter (20) of Wilk and the heart wall of Wilk is construed to be outside the blood vessel; see Figures 3A to 3E, 4, and Figures 5A to 6C as well as columns 3 to 5.

Claim 197 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donaldson in view of Leckrone (US 4,747,405) and Wilk (US 5,287,861). Donaldson discloses bypassing a portion of a diseased aorta, but fails to disclose doing so with a laparoscope as claimed; see Figures 2 and 3 as well as column 5, line 67 to column 6, line 24. However, Leckrone teaches that it was known to use endoscopes (i.e. a type of laparoscope) in similar procedures in order to adequately non-invasively use tools within the body; see the abstract and column 6, line 63 to column 7, line 7. Additionally, Donaldson fails to disclose advancing the graft through or inside a lumen to the anastomosis site as claimed. However, Wilk teaches that it was known to use catheters to advance grafts to the anastomosis site; see Figures 3A to 3E, 4, and Figures 5A to 6C as well as columns 3 to 5. Therefore, it is the Examiner's position that it would have

been obvious to advance the graft of Donaldson to the anastomosis site for the same reasons as Wilk and in order to have a less invasive procedure for the patient.

Claims 186-196, 198-201, 260, and 262 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (US 5,287,861) alone.

Wilk meets the claim language where the graft as claimed is the stent of Wilk, and the anastomosis site as claimed is the needle puncture site in the coronary artery of Wilk. Wilk fails to disclose positioning the graft in the catheter as claimed. However, it is the Examiner's position that it would have been clearly obvious to an ordinary artisan to make the catheter and stent as separate elements and then to insert the stent into the catheter in the manner they are shown in Wilk's figures because, in this way, the stent could be used with different catheters and the catheter could be used with different stents or without a stent. In other words, separate manufacturing would increase the usefulness of each of the components.

With regard to claim 191, the passageway is the inside of the stent or the opening in the heart wall.

With regard to claim 193, the stent of Wilk is shown as wires rolled around the longitudinal axis of the stent cylinder. For this reason, the claim language is fully met.

With regard to claims 260 and 262 specifically, the Examiner posits that going from the downstream of the location access would have been considered *prima facie* obvious over Wilk and is only an adjustment based upon the situation where the occlusion (BL) could not be bypassed as shown in the other figures of Wilk.

Art Unit: 3738

Claims 85-89, 91, 95, 97-104, 106, 110-118, 120, 121, 125, 127-130, 141-145, 147, 151, 153-161, 163, 167, 169-174, 176, 180, and 182-185 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaster (US 5,234,447). Kaster anticipates the claim language where the locating step as claimed is the step of inserting the blood vessel into the mandrel of Kaster (see column 2, lines 63-68), the graft as claimed is the blood vessel of Kaster, the advancing step as claimed is shown in Figures 14-19 of Kaster, and the vessel as claimed is the second vessel of Kaster; see column 6, line 5 to column 7, line 20. The removing step as claimed is disclosed on column 7, lines 8-14.

Regarding claim 98, the aorta attachment end does not require the use at an aorta so the claim language is fully met by Kaster.

Regarding claim 121, the staple of Kaster is part of the graft and it is rolled into a cylindrical shape, but portions of the engaging members (44) have linear portions.

Claims 93, 94, 108, 123, 124, 131, 132, 134-136, 140, 149, 150, 165, 166, 178, and 179 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster (US 5,234,447) alone. Kaster meets the claim language as explained supra, but does not disclose using the method thereof specifically on an aorta. However, since Kaster is a generic method of attaching blood vessels in an anastomosis, it is the Examiner's position that it would have been considered *prima facie* obvious to utilize the method of Kaster to anastomize an aorta based upon the need of a patient to have a bypass of a portion of the aorta. Since the Kaster device can be utilized on any blood vessel, it is

Art Unit: 3738

reasonable that it could be utilized on an aorta as well if the same condition from bypass are present as those disclosed by Kaster; see column 1.

Claims 1, 2, 3, 96, 109, 126, 137, 138, 139, 152, 168, and 181 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster (US 5,234,447) in view of Redtenbacher et al (US 4,817,847) or Avant (US 5,047,039). Kaster meets the claim language as explained above but fails to disclose the use of an endoscope or laparoscope during the process as claimed. However, Redtenbacher teaches that endoscopic use during anastomosis procedures was known; see column 3, lines 16-25 and the paragraph bridging columns 6 and 7. Likewise, Avant teaches laparoscopic anastomosis was known; see the title, and abstract. Therefore, it is the Examiner's position that it would have been obvious to use a endoscope or laparoscope in the Kaster procedure so that it could have been performed with greater accuracy and precision due to the greater visibility of the site.

With regard to claims 2 and 3, the use of the procedure on the aorta would have been obvious for the reasons set forth in the preceding rejection.

Claims 90, 92, 105, 107, 119, 122, 133, 146, 148, 162, 164, 175, and 177 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster (US 5,234,447) in view of Palmaz (US 4,733,665). Kaster meets the claim language except for the structure of having the graft entirely within the delivery device as claimed. However, Palmaz teaches that it was known to deliver similar grafts to blood vessels via catheters; see column 1, lines 20-30. Therefore, it is the Examiner's position that it would have been obvious to use a catheter over the mandrel of Kaster for the same

reasons that Palmaz does the same and in order to protect the staple and the bypass blood vessel prior to and during the procedure.

Allowable Subject Matter

Claim 5 is allowed over the prior art of record.

Response to Arguments

Applicant's arguments filed February 3, 2005 have been fully considered but they are not persuasive.

In response to the traversal of the claim 261 rejection utilizing Wilk, the Examiner maintains that the claims are read on by Wilk even though it has been amended; see Figure 3C and column 4 where a distal end of a medical instrument is shown outside the circulatory system (i.e. outside the coronary artery) where the proximal end is within the coronary artery.

Based upon the fact that the claims were amended, new grounds of rejections were applied. None of the remaining arguments are specifically drawn to any particular claim that was previously rejected. For this reason, the remaining arguments are considered moot.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3738

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul B. Prebilic
Primary Examiner